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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,760	07/17/2003	David L. Lewis	Mirus.030.09.2	9319
25032	7590	09/19/2006		
MIRUS CORPORATION 505 SOUTH ROSA RD MADISON, WI 53719			EXAMINER POPA, ILEANA	
			ART UNIT 1633	PAPER NUMBER

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/621,760

Applicant(s)

LEWIS ET AL.

Examiner

Ileana Popa

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-9 is/are rejected.
- 7) ☒ Claim(s) 6-9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

2. Claim 4 has been cancelled. Claim 1 has been amended to recite delivery *in vitro*. No new matter was introduced by this amendment.

Claims 1-3 and 5-9 are pending and under examination.

### ***Oath/Declaration***

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because the application number and the filing date are missing.

### ***Claim Objections***

4. Claims 6-9 are objected to under 37 CFR 1.75(c) as being in improperly dependent on claim 6. Amending the claims such as to recite "the process of claim 5" would obviate this objection.

***Response to Arguments***

***Double Patenting***

5. The rejection of claims 1-3 and 5-9 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-7, and 13-17 of the copending Application No. 10/157,657 and over claims 1, 2, 4, 5, and 11 of the copending Application No. 10/345,021 is withdrawn in response to Applicant's arguments filed on 07/05/2006.

***Claim Rejections - 35 USC § 103***

6. The rejection of claims 1-3, 7 and 8 under 35 U.S.C. 103(a) as being unpatentable over Wolf et al. (US Patent 5,744,335) in view of Wolfert et al. (Bioconjugate Chem, 1999, 10: 993-1004) is withdrawn in response to Applicant's amendment to claim 1, filed on 07/05/2006.

7. Claims 5, 6, and 9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf et al. (US Patent 5,744,335) in view of Wolfert et al. (Bioconjugate Chem, 1999, 10: 993-1004) for the reasons of record set forth in the previous Office Action. Applicant's arguments filed 07/05/2006 have been fully considered but they are not persuasive.

Applicants traversed the instant rejection on the grounds that the amendment to claim 1 overcomes the rejection. Additionally, Applicants argue that one of skill in the art would not have been motivated to combine the teachings of Wolff et al. with those of

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Wolfert et al. for the following reasons: (i) Wolff et al. clearly teach differences between polycationic DNA-binding proteins (i.e., histones) and other types of polycationic polymers and accordingly, they teach only the use of histones to form efficient transfection complexes, and (ii) Wolfert et al. teach that polyvinylamine by itself has limited *in vitro* transfection ability. For these reasons, Applicants request the withdrawal of the rejection.

Contrary to Applicants assertion, the amendment to claim 1 does not overcome the rejection of claims 5, 6, and 9 because they are drawn to a cell *in vivo* and therefore, the rejection under 35 U.S.C. 103(a) still applies to these claims (see the previous Office Action). It is noted that claims 5 and 9 do not specifically disclosed that the animal cell is *in vitro*. Regarding the Wolff et al., the reference clearly teaches that polylysine, also efficient as a transfection agent, has disadvantages over histone because it induces anaphylactic shock and it is immunogenic. Wolff et al. do not teach that polyvinylamine is not effective as a transfection agent when used in combination with the amphipatic compound or that polyvinylamine has disadvantages as a transfection agent. Therefore, one of skill in the art would have been motivated to combine the teachings of Wolff et al. with those of Wolfert et al. to obtain small and stable complexes for *in vivo* delivery (see the prior Office Action).

***New Rejections***

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-3 and 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf et al., in view of Meier et al. (U.S. Patent No. 6,616,946).

Wolf et al. teach process of delivering a polynucleotide into a cell (i.e., the cell can be *in vivo*, *in vitro*, *ex vivo* or the cell is a mammalian cell), by delivering to the cell a composition comprising an amphipatic compound, a histone, and a selected polynucleic acid, wherein the polynucleic acid can be RNA in the form of oligonucleotide (i.e., the RNA can be siRNA) (Summary of the invention, column 7, lines 17-20). The amphipatic compound is a 1,4 disubstituted piperazine, wherein the substituting groups are C6 to C24 alkenes (column 2, lines 40-52). Wolf et al. do not teach polyvinylamine. Meier et al. teach delivery particles formed from a pH-sensitive polymer such as polyvinylamine for the encapsulation and release of diverse agents under extremely mild conditions, wherein the agents could be a nucleic acid molecule (column 2, lines 4-10, column 6, lines 5-11, column 15, lines 22-25). It would have been obvious to one of skill in the art, at the time the invention was made, to for the deliverable composition of Wolf et al. by

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using polyvinylamine to obtain particles for the controlled delivery of siRNA, with a reasonable expectation of success. The motivation to do so is provided by Meier et al., who teach particles made from polyvinylamine as useful for the controlled delivery the active agent in response to a stimulus supplied at the point of the desired delivery (column 2, lines 29-42). One of skill in the art would have been expected to have a reasonable expectation of success in making and using such a composition because the art teaches that ternary complexes between nucleic acids, amphipatic molecules and polycations can be obtained and successfully used to transfer nucleic acids into cells both *in vivo* and *in vitro*. Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

### **Conclusion**

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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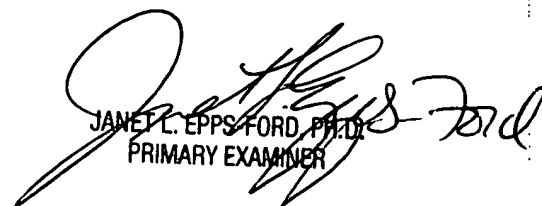
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ileana Popa whose telephone number is 571-272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ileana Popa, PhD

  
JANET L. EPPS FORD, PH.D.  
PRIMARY EXAMINER